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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

EVERAGE, KEVIN D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

08/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/582,847

Applicant(s)

SELIKTAR ET AL.

Examiner

KEVIN EVERAGE

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 134-177 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 134-177 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-850)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 14 June 2006 & 26 May 2009

DETAILED ACTION

Response to Amendment

1. Applicant's amendment filed June 14, 2006 is fully considered. Claims 1-33 have been cancelled. New claims 134-177 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 134-140, 143-146, 172-177 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Desai et al. (US 5,550,178).**

Desai et al. ("Desai") discloses methods of preparing a substantially biodegradable polymer film comprising:

crosslinked polyethylene glycol (PEG) (see column 5, lines 14-24) capable of undergoing free radical polymerization (see column 5, lines 34-45);

an ionically crosslinked, biologically derived polymer (albumin- see column 2, lines 27-39; alginate- see column 5, lines 14-24);

further comprising at least one drug (see column 3, lines 45-50); and

wherein the drug is a growth factor (see column 7, lines 63-67).

4. **Claims 134, 141, 142, 147-151, 154, 158-163, 165, 166, 170 and 171 are rejected under 35 U.S.C. 102(b) as being anticipated by Tartaglia et al. (US 5,637,113).**

Tartaglia et al. ("Tartaglia") discloses a medical device comprising:
an expandable stent (20) covered by a polymer film (24) including cross-linked polyethylene glycol (PEG) (see column 2, lines 56-67);
wherein said stent is a balloon expandable stent (see column 4, lines 44-46);
wherein said polymer film further comprises a biologically derived polymer (see column 2, lines 56-67);
wherein said polymer film further comprises an anti-thrombogenic or anti-restenotic vascular re-healing drug (see column 1, lines 57-64);
wherein the rolled polymer film is unrolled in the lumen of a blood vessel thereby exposing the luminal wall of the vessel to a substance (see column 7, lines 18-22); and
wherein inserting the rolled polymer is effected using a catheter (see column 4, lines 44-46).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 152, 153, 155, 156, 157 and 167-169 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tartaglia et al. (US 5,637,113) in view of Desai et al. (US 5,550,178).**

Tartaglia discloses a polymer film deployed by a balloon expandable stent but does not disclose the stent being self-expandable. However, Tartaglia discloses the stent being comprised of nickel-titanium alloy (nitinol; see column 5, lines 18-48), a known shape memory polymer. It would have been obvious to someone of ordinary skill in the art at the time of the invention to exploit the shape memory characteristics of the nitinol stent to make the stent self-expandable being that both nitinol and self expandable nitinol were very well known in the art.

Tartaglia discloses the polymer film comprising cross-linked PEG but does not disclose the film being biodegradable or comprising alginate. However Desai discloses a polymer film having these characteristics (see 35 U.S.C. 102 rejections above references Desai et al.). Being that the polymer films disclosed by Desai and Tartaglia both predate the applicant's invention and are similarly useful in delivering therapeutic drugs to target blood vessel sites, it would have been obvious to someone of ordinary skill in the art that the polymer film disclosed by Desai could be deployed using the system disclosed by Tartaglia.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN EVERAGE whose telephone number is (571)270-7485. The examiner can normally be reached on 9-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN EVERAGE
Examiner
Art Unit 3734

/K.E./

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773